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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Opportunity to Co-Sponsor Office for Human Research Protections Research Community Forums

AGENCY: Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Office for Human Research Protections (OHRP) announces the opportunity for non-federal public and private sector entities to co-sponsor OHRP Research Community Forums (RCFs). Potential co-sponsors must have an approved Federal-wide Assurance with OHRP, be recipients of HHS grants for human subject research, and have a demonstrated interest and experience in the protection of human subjects in research. Potential co-sponsors must also be capable of sponsoring and managing various discrete sessions or events associated with the RCF and be willing to participate substantively in the co-sponsored activity.

DATES: Requests for co-sponsorships of RCFs are received throughout the year at the address below. OHRP expects to co-sponsor up to four RCFs each year. Requests are being received for RCFs that will take place in 2018 or beyond.

ADDRESSES: Requests for co-sponsorships should be sent to OHRP-EDU@HHS.GOV with "Co-sponsorship for OHRP RCFs" in the subject field or by mail to OHRP at 1101 Wootton Parkway, Suite 200, Rockville MD 20852.

SUPPLEMENTARY INFORMATION:

Description

The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and well-being of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). The OHRP is a program office within the Office of the Assistant Secretary for Health, Office of the Secretary, HHS.

OHRP provides clarification and guidance, develops educational programs and materials, maintains regulatory oversight, and provides advice on ethical and regulatory issues in biomedical and behavioral research. OHRP also supports the Secretary's Advisory Committee on Human Research Protections (SACHRP), which advises the Secretary of Health and Human Services on issues of human subject protections.

Consistent with OHRP's mission and the applicable statutory authority, 42 U.S.C. 289, the Research Community Forum (RCF) provides an educational opportunity to discuss with the public and to provide clarification and guidance regarding contemporary ethical issues in the protection of human research participants. The Research Community Forum (RCF) consists of two educational activities: a 1-day conference (RCF-C) focused on ethical concerns and regulatory issues pertaining to contemporary issues in human research protections, and a 1-day interactive workshop (RCF-W) focused on the interpretation and application of HHS regulations and policies. OHRP will provide a small co-sponsoring financial contribution to support the RCF.

Co-sponsors will assist with conference and agenda development, coordination, financial management, and meeting logistics in conjunction with OHRP staff.

Co-sponsors can charge registration fees to recover costs associated with the events; however, co-sponsors may not set registration fees at an amount higher than necessary to recover related conference expenses. Further, we expect co-sponsors to be solely responsible for collecting and handling any registration fees collected.

Eligibility for Co-Sponsorship: The co-sponsoring institution must have an approved Federal-wide Assurance with OHRP and be a recipient of HHS grants for human subject research. The selected co-sponsoring organization(s) shall furnish the necessary

personnel, materials, services, and facilities to administer its responsibility for the conference. These duties will be outlined in a co-sponsorship agreement with OHRP that will set forth the details of the co-sponsored activity, including the requirements that any fees collected by the co-sponsor shall be limited to the amount necessary to cover the co-sponsor's related conference expenses.

Co-sponsoring institutions will be asked to sign a Co-Sponsorship Agreement with HHS. This Co-Sponsorship Agreement does not represent an endorsement by OHRP of the co-sponsors' policies, positions, or activities. Additionally, this Agreement will not affect any determination concerning activities by the co-sponsors that are regulated by OHRP.

The following Model Co-Sponsorship Agreement is presented only as an example. The assignment of duty and responsibilities in the Agreement will be discussed and agreed upon with each o-sponsor on a case by case basis and as applicable.

Model Co-Sponsorship Agreement

The Office for Human Research Protections (OHRP) and [co-sponsor] (if more than one co-sponsor, include all names followed by "jointly referred to as co-sponsoring institutions") agree to co-sponsor a Research Community Forum according to the understanding expressed below:

1. Background

The event is an OHRP Research Community Forum (RCF) tentatively titled, [Title].

The forum will be held on [Date] at [Location].

The Forum is a 2-day educational outreach initiative that provides a 1-day conference focusing on ethical and regulatory issues pertaining to hot-button or topical matter in human research protections, and a 1-day interactive workshop focusing on the HHS regulations and policies on human research protections and their applicability. The Forum features distinguished faculty members from academia and the Federal Government. It is designed for professionals engaged in or who have interest in the protection of human subjects in research. These may include bioethicists, academics, institutional review board (IRB) chairs, members and staff, investigators and research staff, and institutional officials.

The co-sponsoring institution for this educational event, [co-sponsor], has an approved Federal-wide Assurance with OHRP and is a recipient of HHS grants for human subject research. OHRP has collaborated with [co-sponsor] (if more than one co-sponsor, include: ", [co-sponsor], and others.") to develop a comprehensive agenda that addresses the provisions of the HHS Protection of Human Subjects Regulations, 45 C.F.R. Part 46, and the ethical principles of The Belmont Report.

OHRP fulfills its mission, pursuant to 42 U.S.C. 289, by providing an education program where clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects can be addressed. This forum co-sponsored with [co-sponsor] is an important component of the OHRP educational program for fiscal year [year].

2. Responsibilities for Developing the Event

OHRP and [Co-sponsor] have collaborated, and will continue to collaborate, on all phases of event planning, including:

- Establishing a planning committee;
- Identifying program objectives;
- Developing, reviewing and approving the final agenda; and
- Preparing web-based advertising.

[Co-sponsor] has or will:

- Create an event website;
- Secure a facility for the Forum (conference and workshop);
- Provide audio-visual equipment;
- Arrange for professional video-recording of presentation(s) by speaker(s) [XXX] at OHRP's request;

- Handle or support the collection of registration fees;
- Provide administrative staff to develop the program, conduct registration, obtain accreditations for continuing education units as appropriate and handle all logistical support leading up to and at the forum;
- Provide travel expenses for additional academic faculty;
- Duplicate all forum materials and prepare participant notebook as appropriate;
- Distribute and collect from speakers signed authorization forms (wording and format provided by OHRP) that permit OHRP to retain and re-use speakers' presentations as well as any video recordings of the presentations obtained in the course of the Forum for educational purposes;
- Provide OHRP with copies of the speakers' slide presentations (slides and any associated video recordings), as well as any video-recordings of conference presentations obtained in the course of the Forum, no later than 4 months after the RCF;
- Produce and share with OHRP a summary and evaluation report as well as the list of participants with their email information.

3. Registration Fees and Other Charges

[Co-sponsor] has established a tentative registration fee schedule, $[Amount] for the 1-day conference; $[Amount] for the 1-day workshop; and $[Amount] when registering for both conference and workshop. These registration fees are no higher than necessary for [co-sponsor] to recover its share of the costs for co-sponsoring this event and may be lowered, as the arrangements for the forum event are made and expenses are incurred.

HHS staff will be serving as faculty members and resource people. There is no attendance fee for HHS staff.

[Co-sponsor] does not intend to sell educational materials pertaining to this event.

4. Independently Sponsored Portions of Event

[Co-sponsor] may decide to independently provide food for lunch and/or at breaks for the Workshop/Event attendees as a discrete portion of the event. The workshop/event agenda will indicate that this portion of the event is independently sponsored by [co-sponsor]. OHRP staff and resources will not be used to develop, promote, or otherwise support this portion of the event.

5. Fund Raising

[Co-sponsor] will make clear in any solicitation for funds to cover its share of the event costs that it, not OHRP, is asking for the funds. [Co-sponsor] will not imply that OHRP endorses any fund raising activities in connection with the Forum.

[Co-sponsor] will make clear to donors that any gift will go solely toward defraying the sponsorship expenses of the event, not to OHRP.

6. Promotional Activity

[Co-sponsor] will not use the event primarily as a vehicle to sell or promote products or services. [Co-sponsor] will ensure that any incidental promotional activity does not imply that OHRP endorses any of its products or services. [Co-sponsor] will make reasonable efforts, subject to OHRP review, to segregate any incidental promotional activity from the main activities of the event.

7. Event Publicity and Endorsements

[Co-sponsor] will not use the name of OHRP or any of its components, except in factual publicity for the specific event. Factual publicity includes dates, times, locations, purposes, agendas, fees, and speakers involved with the event. Such factual publicity shall not imply that the involvement of OHRP in the event serves as an endorsement of the general policies, activities, or products of [co-sponsor]; where confusion could result, publicity should be accompanied by a disclaimer to the effect that no endorsement by OHRP is intended. [Co-sponsor] will clearly state on the agenda that OHRP did not provide funding for the breaks and lunch at the forum. [Co-sponsor] will state on the agenda which organization provided the funding for the breaks and lunch at the forum. [Co-sponsor] will clear all publicity materials for the event with OHRP to ensure compliance with this paragraph.

8. Records

Records concerning the event shall account fully and accurately for the financial commitments and expenditures of OHRP and [co-sponsor]. Such records shall reflect, at a minimum, the amounts, sources, and uses of all funds.

9. Public Availability

This co-sponsorship agreement, as well as the financial records described in paragraph 8, shall be publicly available upon request.

10. Co-sponsorship Guidance

OHRP and [co-sponsor] will abide by the legal memorandum of August 8, 2002, "Co-Sponsorship Guidance," issued by the HHS Designated Agency Ethics Official.

EVALUATION CRITERIA: After engaging in exploratory discussions with potential co-sponsors, OHRP will select the co-sponsor or co-sponsors that would best fulfill OHRP's mission. Evaluation may include the following criteria:

- Qualifications and capability to fulfill co-sponsorship responsibilities;
- Suitability of the location of the proposed event in terms of the overall geographical distribution of OHRP-RCFs;

- Interests in human research protections that complement and promote OHRP's interests and agenda;
- Creativity and innovations related to the human research protections topics proposed to cover;
- Creativity in enhancing the conference, including ideas for improving the event based on prior RCFs;
- Potential for reaching, generating, and engaging attendees from diverse key stakeholders;
- Availability and description of facilities needed to support the RCF;
- Availability of administrative expertise, experience, and support (including accounting and event management) for the logistics of hosting events of a similar scale.

FOR FURTHER INFORMATION CONTACT: OHRP-EDU@HHS.GOV or call OHRP's Division of Education and Development (DED) at 240-453-6900.

Dated: June 29, 2016.

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